

label linked to a coreactant wherein the coreactant is not an analyte of interest. New claim 22 is directed to compounds which comprise electrochemiluminescent label linked to a coreactant wherein the linkage comprise one or more groups for attachment of biomolecules. Support for new claims 20- 22 is found at page 17, lines 9-22.

Thus, claims 3, 4 and 7-22 are currently pending in the present application. Claims 3-4, and 7-18 have outstanding issues from the Final Office Action dated June 20, 1990 which was issued in the parent U.S.S.N. 08/936,971 application ("Final Office Action"). Reconsideration and withdrawal of the rejections set forth in the Final Office Action in view of the remarks set forth below is respectfully requested.

In the Final Office Action, the Examiner stated as a new ground of rejection that the original declaration as filed is defective because it failed to claim priority to all of the applications set forth in the amended priority claim. Applicants are in the process of preparing a new declaration to correct the priority claim.

The Examiner made the following rejections in the Final Office Action:

(i) Claims 3-4, 7-8, 9-12 and 15-18 rejected under 35 U.S.C. 112, first paragraph, because the specification did not reasonably provide enablement for any coreactant.

(ii) Claims 3-4, 7-8, and 9-18 rejected under 35 U.S.C. 112, second paragraph as indefinite because:

a. the term coreactant, which includes both precursor species and species capable of undergoing transformation to form interactive species, is unclear; and

b. the term "linked" is unclear.

(iii) Claims 3-4, 9, 15, 17, and 18 rejected under 35 U.S.C. 102(b) as anticipated by Massey WO 87/06706 ("Massey '706").

- (iv) Claims 3-4, 7-8, 9, 10, 15, 17, and 18 rejected in view of Massey U.S. Pat. 5,591,581 (“Massey ‘581”):
- a. Claims 3-4, 9, 10, 15, 17, and 18 rejected under 35 U.S.C. 102(e) as anticipated by Massey ‘581
 - b. Claims 7-8 rejected under 35 U.S.C. 103(a)/102(e) over Massey ‘581.
 - c. Claims 3-4, 7-8, 9, 10, 15, 17, and 18 rejected under 35 U.S.C. 103(a)/102(f) and (g) over Massey ‘581.
 - d. Claims 3-4, 7-8, 9, 15, 17, and 18 rejected under the judicially created doctrine of obviousness-type double patenting over Massey ‘581 claims 1-6, 19, and 20.
- (v) Claims 3, 4, 7-8, 9, 15-18 rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Pat. 5,643,713 (“Liang”) claims 1-6, and 19.
- (vi) Claims 10-12 and 17 rejected under 35 U.S.C. 112, first paragraph, for lack of written description support for tertiary amine, dipropyl amine, N,N, dipropylamino acids, strong reductant, and strong oxidant.
- (vii) Claims 17 and 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the terms “strong” in claim 17 and the coreactant species of claim 18.
- (viii) Claims 3-4, 7-8, 9, 13, 17 and 18 rejected in view of U.S. Pat. 4,293,310 (“Weber”):
- a. Claims 3-4, 7-8, 9, 13, 17 and 18 rejected under 35 U.S.C. 102(b) as anticipated by Weber
 - b. Claims 7-8 rejected under 35 U.S.C. 103(a)/102(e) over Weber.

Applicants respectfully traverse each of the aforementioned grounds for rejection below.

I. **Claims 3-4, 7-8, 9-12 and 15-18 Are Enabled By The Specification**

The subject matter of claims 3-4, 7-8, 9-12 and 15-18 has been rejected under 35 U.S.C. § 112, first paragraph allegedly because the specification, while being enabling for specific coreactants disclosed, does not reasonable provide enablement for any coreactant. Similarly, the Examiner has alleged that the preparation and use of coreactants which are present as precursors or species which can be transformed into a coreactant coupled to a generic electrochemiluminescence (“ECL”) label do not appear to be within the scope of reasonable experimentation.

Applicants respectfully disagree and request that the Examiner reconsider this rejection with the following in mind. The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. In re Marzocchi, 169 U.S.P.Q. 367 (CCPA 1971). An assertion by the Patent Office that the enabling disclosure is not commensurate with the scope of the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. In re Dinh Nguyen, 181 U.S.P.Q. 46 (CCPA 1974); In re Brown, 181 U.S.P.Q. 48 (CCPA 1974); In re Armbruster, 185 U.S.P.Q. 152 (CCPA 1975).

As set forth in the specification, the present invention relates to a compound which comprises an electrochemiluminescent label (EL) linked to a coreactant (CR) which compound emits ECL when exposed to electrochemical energy.

Applicants agree that the factors to be considered in determining undue experimentation are those set forth in the case of In re Wands, 8 U.S.P.Q.2d 1400 (CAFC 1988). The relative skill in the art is high. Additionally, at the time of invention, a great deal was known about ECL labels and ECL coreactants. For example, a number of different classes of ECL labels were known in the art at the time of the invention. U.S. Patent No. 5,310,687 incorporated by

reference in the present application, as well as in the 5,643,713 parent application, disclose Ru and Os containing labels (col. 5, line 65 - col. 6, line 15 of the '713 patent) as well as a variety of other types of ECL labels (col. 19, lines 50-60). Moreover, the present application also teaches ECL labels other than Os, Ru and Re complexes. See specifically the list of ECL labels which contains a metal set forth at pages 23-25 of the specification.

The present application also includes by reference a paper by Knight et al. entitled "Occurrence, Mechanism and Analytical Applications of Electrogenenerated Chemiluminescence", Analyst, 119, 879 (1994), which was previously submitted as Exhibit B in the Amendment submitted on December 22, 1999. Knight lists many additional ECL labels in Table 1 thereby providing an indication of the knowledge and level of skill in the art at the time of the invention. The Knight paper describes some ECL mechanisms believed to be common to large classes of ECL labels. See specifically reactions 1-4, 7-8 and 13-18 cited therein. The Knight paper also notes criteria that one skilled in the art could use to select appropriate inorganic ECL labels as described in the last paragraph on page 883.

Preferred ECL labels of the present invention include Ru and Os containing complexes. These compounds are advantageous due to their strong electrochemiluminescence. However, Knight shows that other ECL labels that operated according to similar mechanisms were known and that criteria necessary for selecting other labels were also known. Given the high level of skill in the art as shown by Knight, one skilled in the art would be able to select other labels for use in the compounds of the invention and expect the compounds to function in a similar manner.

The present application also provides enablement for a coreactant which when linked to an ECL label emits ECL when exposed to electrochemical energy. The specification clearly

defines the properties of an ECL coreactant "CR" at page 6, lines 13-20. Furthermore, the application provides a description of properties of CRs that would guide one skilled in the art towards selecting appropriate moieties. See also page 10, line 18 - page 12, line 25. The application also lists numerous coreactants that can be used in the invention at page 10, lines 5-9 and page 13, line 11 - page 14, line 21. U.S. Patent No. 5,310,687, incorporated by reference on Page 15, line 10 of the specification, describes a proposed mechanism of the coreactant TPA (page 5, lines 54-67) and also describes how the ability of other molecules to act as coreactants (such as hydrolyzed β -lactams or NADH) can be predicted from similarities in structure to known coreactants such as TPA.

The scientific paper to Knight et al. also provides support for a coreactant in column 1 on page 881 in the last paragraph starting with the language "A suitable donor or acceptor molecule". Additionally, on page 884 in col. 1, page 884, in the language set forth after reaction (16) starting at "Alternatively, by the use of strongly oxidizing or reducing species in solution" et seq. Thus, the Knight reference provides an indication of the state of the art of ECL labels and coreactants around the time of the invention. The Knight et al. reference, however, does not disclose any advantage to be gained by linking an EL with a CR. Nevertheless, one skilled in the art, once in possession of the teachings of the present invention can use the electrochemiluminescent labels and coreactants disclosed in the Knight et al. reference to generate EL-CR conjugates.

Finally, Applicants submit that enablement is not precluded even where the disclosure requires some experimentation. In fact, a considerable amount of experimentation is permissible. See, In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Because the relative skill of those in the art is high, the threshold point at which experimentation becomes undue must

also be high. Given this, Applicants submit that, based on the instant specification, one skilled in the art would not have to engage in undue experimentation in order to practice the invention as claimed. Thus, the specification provides a description sufficient to enable one of ordinary skill in the art to make the claimed invention without undue experimentation.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). [MPEP § 2164.01(b)]. Thus, there is no need to limit the claims to the specific coreactants disclosed in, for example, the Knight reference or the specification.

Accordingly, Applicants respectfully submit that additional examples of the complexes of ECL labels linked to coreactants are not necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention [MPEP §2164]. A patent does not teach, **and preferably omits**, what is well known in the art. In re Buchner, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). [See, MPEP § 2164.01].

As stated before, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue. In re Angstadt, 190 U.S.P.Q. 214 (CCPA 1976). [See, MPEP § 2164.01]. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. In re Certain Limited - Charge Cell Culture Microcarriers, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n

1983); MIT. v. A.B. Fortia, 227 U.S.P.Q. 428 (Fed. Cir. 1985); In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). [See, MPEP § 2164.01].

Applicant submits that it is improper to reject claims on the ground that the specification does not support the claims when the terms are no broader than the broadest description of the invention in the specification and there is no reason to challenge the operativeness of the subject matter embraced by the claims. Ex parte Altermatt, 183 U.S.P.Q. 436 (POBA 1974).

Applicant urges that in order to make a rejection, the Examiner has the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). [See, MPEP §2164.04]. The Examiner has failed to present any evidence or reasoning substantiating the allegation that the presently claimed subject matter is not enabled. Accordingly, the burden of proving enablement has not shifted to the Applicant and therefore the rejection is improper.

Thus, Applicants respectfully request the withdrawal of the rejection of claims 3-4, 7-8, 9-12 and 15-18 under 35 U.S.C. § 112, first paragraph.

II. **Claims 3-4, 7-8, and 9-18 Are Definite**

Claims 3-4, 7-8 and 9-18 have been further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants believe that there is no basis for such rejection. Applicants urge that the terms in the patent claims are not too vague unless they prevent one skilled in the art from understanding, in light of the specification, what is claimed. Andrew Corp. v. Gabriel Electronics, Inc., 6 U.S.P.Q. 2d 2010 (Fed. Cir. 1988); U.S. v. Teletronics, Inc., 8U.S.P.Q. 2d 1217 (Fed. Cir. 1988); Specialty Composites v. Cabot Corp., 6 U.S.P.Q.2d 1601 Fed. Cir. 1988).

Applicants respectfully submit that if the scope of subject matter embraced by a claim is clear and if the Applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim particularly points out and distinctly claims the subject matter which the applicant regards as his invention. In re Borkowski, 164 U.S.P.Q. 642 (CCPA 1970); In re Robins, 166 U.S.P.Q. 552 (CCPA 1970). Breadth alone is not indefiniteness. In re Gardner, 166 U.S.P.Q. 138 (CCPA 1970;); In re Conley, 180 U.S.P.Q. 454 (CCPA 1974); Ex parte Lewis, 197 U.S.P.Q. 543 (Bd. App. 1977).

A fundamental principle contained in 35 U.S.C. § 112, second paragraph, is that Applicants are their own lexicographers. Applicants can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicants may use functional language, alternative expressions, negative limitations, or any style of expression or format of a claim which makes clear the boundaries of the subject matter for which protection is sought (MPEP, Section 2173.01). A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. In re Swinehart, 160 U.S.P.Q. 226 (CCPA 1971). Applicants respectfully submit that the Examiner's focus during the examination of claims for compliance with 35 U.S.C. § 112, second paragraph, is whether the claims meet the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available (MPEP, Section 2173.02).

Based on the definitions now present in the specification, Applicants urge that the definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art

at the time the invention was made (MPEP, Section 2173.02). Applicants urge the claims fully meet the requirements of 35 U.S.C. § 112, second paragraph.

The definition of coreactant on page 6 is limited in the claims by the fact that when linked to an ECL label and exposed to electro-chemical energy the resulting compound emits electroluminescence. Moreover, the definition of coreactant on page 6 is also supplemented with a great deal of detail on pages 9 to page 17 of the specification. Contrary to the Examiner's contention that "it would be unclear what process the attached molecule might be subject to that may transform it into a coreactant," the specification describes in great detail at page 10, line 19 et seq. processes that could be undergone by CRs which are oxidant or reductant precursors. Nevertheless, in order to expedite the prosecution of this application and render the language of the claims even clearer Applicants are willing to incorporate in the main independent claims the limitations of claim 18.

The Examiner has also found the term "linked" to be vague and indefinite. The term "linked" is based on the fact that there is a linkage between CR and EL. Linkage has been defined in great detail starting at page 17, line 8 to page 21, line 9 of the specification. In view of the very detailed definition of linkage in the specification, Applicants urge that since the analysis of the terms of the claims will be conducted by one skilled in a highly developed art, the term "linked" which is based on linkage is neither vague nor indefinite. Thus, the rejection based on 35 U.S.C. § 112, second paragraph is inappropriate and should be withdrawn.

**III. Claims 3-4, 9, 15, 17, and 18 Are Novel
Under 35 U.S.C. 102(b) Over Massey '706**

Claims 3-4, 9, 15, 17 and 18 have been rejected under 35 U.S.C. §102(b) as being anticipated by Massey '706. More specifically, the Examiner alleges that on page 193, the Massey '706 discloses theophylline linked to Ru(bpy)₃²⁺ which meets the limitations of the

claim. Applicants respectfully disagree. Theophylline as disclosed on page 193 of the cited reference is an analyte of interest and not a coreactant or a chemically transformable first compound as defined in the Applicants' specification at page 6, line 13 et seq. Theophylline is used to bind another entity such as an antibody with which it forms a complex. As such theophylline does not play a role in the actual emission of ECL. Therefore, the rejection based on the Massey '706 reference is inappropriate and should be withdrawn. Furthermore, Massey '706 does not teach or suggest Applicants' dependent claims 17 or 18, or new dependent claims 20-22 where it is expressly clear that a coreactant is not an analyte of interest.

**IV. Claims 3-4, 9, 10, 15, 17 and 18 Are Novel
And Nonobvious Over Massey '581**

A. 35 U.S.C. 102(e)

Claims 3-4, 9, 10, 15, 17, and 18 have also been rejected under 35 U.S.C. § 102(e) as being unpatentable over Massey '581. More specifically, the Examiner alleges that Massey '581 discloses ECL labels with a coordinated Re atom linked to numerous B compounds where B can be peptides, nucleic acids, polysaccharides and other moieties recited in claim 1 of the '581 patent. The Examiner further alleges that as a coreactant includes precursor species and species which upon chemical transformation result in species which can interact with the label to induce electrochemiluminescence Massey '581 anticipates claims 3-4. Applicants respectfully disagree. The Massey '581 patent does not disclose B as a precursor species or species which undergoes a chemical transformation and thereafter interacts with an ECL label via a linkage to produce ECL.

Furthermore, the amines cited by the Examiner in the '581 patent (e.g., col. 15, lines 1-15 and col. 30, line 38- col. 31, line 37) are part of the compound and are not disclosed as coreactants as defined in the Applicants' specification at page 6, line 13 et seq. Contrary to the Examiner's assertion, the amines bounded to the Re in the '581 patent here are not coreactants as

defined by the Applicants' specification, but are part of the Re label compound itself. Re by itself is not a label: it will not emit light (i.e., will not luminesce). Re must be part of an organometallic complex in order to be a label which emits light (i.e., luminesce). The amines disclosed in the Massey '581 allow for better ligand binding to the Re to form this organometallic complex label compound. If these amines were oxidized or reduced as a coreactant would be, it would in effect destroy the photophysical property of the Re compound label to emit light (i.e. to luminesce) - this is contrary to the function of a coreactant.

In order to have a valid 102 type rejection all the elements of the rejected claims must be disclosed in the cited reference. To the extent that a CR linked to an EL is not disclosed, the '581 patent cannot anticipate the claims. Accordingly, this rejection is inappropriate and should be withdrawn.

B. 35 U.S.C. 103(a)/102(e)

The Examiner has further rejected claims 7 and 8 under 35 U.S.C. §103(a) based on 102(e) over the Massey '581 patent. The arguments made in connection with the 102(e) rejection with respect to claims 3-4, 9, 10, 15, 17 and 18 apply here as well. Additionally, there is no teaching in the '581 patent that would provide a multiplication to change the disclosure of the '581 patent as proposed by the Examiner. Accordingly, this rejection is inappropriate and should be withdrawn.

C. 35 U.S.C. 103(a)/102(f) and (g)

Claims 3-4, 7-8, 9, 10, 15, 17 and 18 have also been rejected under 103(e) based upon the reference applied under 102(f) and 102(g) as being unpatentable over the '581 patent to Massey et al. Additionally, the Examiner further rejected claims 3-4, 7-8, 9, 15, 17 and 18 as not being patentably distinct from claim 1-6, 19 and 20 of the Massey '581 patent. Specifically, the

Examiner requests a showing that the conflicting inventions were commonly owned at the time of the invention of this application. Applicants hereby state that these inventions were all commonly owned at the time of the invention of this application. As with the Liang reference, Applicants have already submitted as Appendix A in the December 22, 1999 Amendment copies of executed Employee Proprietary Information Agreement which under clause 6 indicate that as employees of the assignee company, the assignor inventions are bound to assign and agree to assign to IGEN, the assignee, all their rights, title and interest in and to all invention . . . which the inventor solely or jointly conceives or reduces to practice during the term of his/her employment. If deemed absolutely necessary for the Massey '581, Applicants can provide employment agreements of all these inventors too showing an obligation to assign to the same assignee. Since all of the inventors were employed at the time of filing of this application and had been hired prior to such date, it is respectfully submitted that an assignment as of the filing date of this application and in fact as of the date of conception has been established. Thus, even assuming arguendo that the subject matter of the '581 patent might otherwise qualify as prior art under 35 U.S.C. 102(f) or (g), the patentability of the subject matter of the claims of the present application is not precluded, because the inventors of the '581 patent and the present application were at the relevant time owned by the same entity or subject to an obligation of assignment to the same entity.

In further response to these rejections, Applicants advise that application No. 08/227,898 which issued as U.S. Patent No. 5,591,581 has been commonly owned by the same entity, namely IGEN International Inc. The '898 application which is a continuation-in-part of 07/533,931, filed June 5, 1990, which is a continuation of 07/117,017 filed November 4, 1987,

now abandoned, which is a continuation-in-part of 06/858,354 filed on April 30, 1986, now abandoned has been recorded on January 25, 1988 on Reel 4878/Frame 0008.

D. Judicially Created Obviousness-Type Double Patenting

The rejection of claims 3-4, 7-8, 9, 15, 17, and 18 under the judicially created doctrine of double patenting over claims 1-6, 19 and 20 of the commonly assigned Massey '581 patent is believed to be unwarranted.

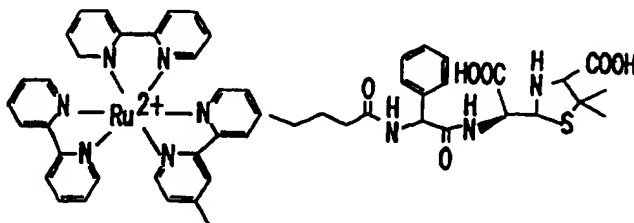
The doctrine of double patenting functions to preclude the same inventor or assignee from extending the statutory patent term via securing of a second patent on the same invention or an obvious variant thereof. The focus of any double patenting analysis is on the claims in the patents or patent applications involved. MPEP §804.

The terminology of the claims in the instant application is defined in the specification. On page 6, line 13 of the specification a coreactant (CR) is defined to encompass species which are (i) capable of interaction with an electrochemiluminescent label (EL) to result in electrochemiluminescence, (ii) precursor species which upon exposure to electrochemical energy are transformed into such interactive species, and (iii) species which are capable of undergoing a chemical transformation to form said interactive species or said precursor species. Additionally, as stated on page 10, line 5 et seq., some examples of known CR species include amines, peroxides, persulfates, oxalates and cofactors (e.g. NADH). As stated on page 9, line 16, in certain good embodiments, the EL is linked to an electrochemiluminescent reactant (ECR), which category encompasses species which themselves are capable of interaction with an EL to result in electrochemiluminescence, and precursor species which upon exposure to electrochemical energy are transformed into such interactive species.

In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on the same invention. "Same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. MPEP §804.

For example, as applied to the instant application, an amine of the following formula is encompassed in CR-EL and within the application's claims.



However, this compound is not within the scope of claims 1-6 , 19 and 20 of the '581 patent, which claim entirely different chemical moieties.

Furthermore, the cited claims of the '581 patent neither recite nor suggest a CR linked through a linkage to an ECL label. Instead they disclose a Re label linked to a binding entity through one of its ligands. In claims 1-6, 19 and 20 of the '581 patent Re is bound to a

biomolecule useful in a binding assay. Re is not linked to a CR. Moreover, the '581 patent to Massey does not even define a CR in any of the cited claims.

Additionally, contrary to the Examiner's assertion, the amines bounded to the Re in claims 19 and 20 are not coreactants as defined by the Applicants' specification, but are part of the Re label compound itself. Re by itself is not a label: it will not emit light (i.e., will not luminesce). Re must be part of an organometallic complex in order to be a label which emits light (i.e., luminesce). The amines in claims 19 and 20 of Massey '581 allow for better ligand binding to the Re to form this organometallic complex label compound. If these amines were oxidized or reduced as a coreactant would be, it would in effect destroy the photophysical property of the labels in claim 19 and 20 to emit light (i.e. to luminesce) - this is contrary to the function of a coreactant.

Accordingly, Applicants urge that the rejection of claims 3-4, 7-8, 9, 15, 17, and 18 under the judicially created doctrine of obviousness-type double patenting is improper and its withdrawal is respectfully requested.

V. **Liang And The Present Application**

Claims 3-4, 7-8, 9, 15-18 have been rejected under "same invention" doctrine of double patenting over claims 1-6 and 19 of U.S. Patent No. 5,643,713 to Liang. Applicants have previously advised that they are willing to provide a terminal disclaimer disclaiming the remaining term of the present application over the '713 patent without admitting obviousness over the cited patent. Applicants advise that the terminal disclaimer will be provided to overcome this rejection once the claims have been found otherwise in condition for allowance.



VI. **Claims 10-12, 17, and 18 Satisfy 35 U.S.C 112, first paragraph**

Claims 10-12 and 17 were rejected under 35 U.S.C. 112, first paragraph, for lack of written description support for tertiary amine, dipropyl amine, N,N, dipropylamino acids, strong reductant, and strong oxidant. Applicant respectfully traverse.

Support for tertiary amine is found, for example, in Example 2 at page 30, lines 22-26. Dipropyl amine is disclosed, for example, by tripropyl amines and diamines (i.e, p. 13, lines 11-20) and as well as by the N,N dipropyl amino acids in Example 1 (p. 28, lines 6-15). Finally, “strong reductant” or “strong oxidant” is found, for example, in the specification at p. 10, lines 20-24.

Thus, withdrawal of the rejection for claims 10-12, 17, and 18 under 35 U.S.C. 112, first paragraph is respectfully requested.

VII. **Claims 17 and 18 Satisfy 35 U.S.C. 112, second paragraph**

Claims 17 and 18 were rejected under 35 U.S.C. 112, second paragraph, for being indefinite because of the term “strong” and the coreactants of claim 18. Applicants respectfully traverse.

At the outset, it is clear to one skilled in the art what is meant by the term “strong” oxidant or reductant. Assuming arguendo that one skilled in the art would not know what is meant by “strong”, the specification provides a clear standard for ascertaining the requisite degree of strength for the term “strong”. For example, the specification explains on page 4, that Equation 1 may be used to determine “the minimum reducing power of the oxidized, deprotonated amine or amine moiety.” p. 4, lines 6-7 (emphasis added). An example calculation was even performed to illustrate the use of this equation (p. 4, lines 9-22).

Thus, withdrawal of the rejection of claims 17 and 18 under 35 U.S.C. 112, second paragraph is respectfully requested.



VIII. **Claims 3-4, 7-8, 9, 13, 17, and 18
Are Patentable Over Weber**

Claims 3-4, 9, 13, 17, and 18 were rejected under 35.U.S.C. 102(b) as anticipated by Weber. Claims 7-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Weber. Applicants traverse these rejections.

The Examiner comments that the Applicants' claims are anticipated because Weber discloses a morphine linked to the ECL label 4,4'-dicarboxy-2,2'-bipyridinyl-bis(2,2'-bipyridine)Ru linked to morphine via a 3-O morphine ester (col 9, lines 61-68). However, Applicants respectfully direct the Examiner to col. 9, line 64 which clearly states that this compound is the "labeled analyte". This compound is a labeled analyte because the ECL label (4,4'-dicarboxy-2,2'-bipyridinyl-bis(2,2'-bipyridine)Ru) is linked to an analyte (morphine). Thus, the morphine is the analyte of interest, and not a coreactant. Such compound does not disclose each element of the Applicants' claims 3-4, 9, 13, 17, and 18, all of which require a coreactant linked to an electrochemiluminescent label, not a label linked to an analyte.

Thus, it follows that Weber thus cannot render Applicants' claims 7-8 obvious.

Thus, withdrawal of these rejections is respectfully requested.

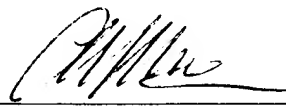


CONCLUSION

In view of the foregoing remarks and amendments, Applicants respectfully submit that claims 3-4 and 7-22 are in condition for allowance and such action is earnestly solicited.

If there are any issues which would remain to prevent these claims from being allowed, the Examiner is respectfully requested to contact the Applicants' undersigned attorney to discuss the matter.

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